

Appl. No. 10/039,753  
Amdt. dated: September 6, 2006  
Response to Office Action of August 17, 2006

**Amendments to the Claims:**  
**Listing of the Claims**

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (currently amended) A method for characterizing a test subject's risk of ~~developing or~~ having atherosclerotic cardiovascular disease, comprising:

determining levels of myeloperoxidase (MPO) activity, myeloperoxidase (MPO) mass, or both in a bodily sample from the test subject, said bodily sample being blood, serum, plasma, blood leukocytes selected from the group consisting of neutrophils and monocytes, or any combination thereof,

wherein elevated levels of MPO activity or MPO mass or both in the bodily sample of the test subject as compared to at least one predetermined value based on levels of MPO activity, MPO mass or both, respectively, in comparable bodily samples obtained from a population of control subjects diagnosed as not having the disease indicates that the test subject is at risk of ~~developing or~~ having atherosclerotic cardiovascular disease.

2. (previously presented) The method of claim 1 wherein the level of myeloperoxidase activity in one or more populations of leukocytes in the test subject's blood is determined by an assay which employs a peroxidase substrate and flow cytometry.

3. (currently amended) The method of claim 1, wherein said predetermined value is a single normalized value or a range of normalized values and is based on the MPO activity levels in comparable bodily samples from the ~~general population or a select population of~~ control subjects.

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4. (currently amended) The method of claim 1 wherein said predetermined value is a single representative value or a range of representative values and is based on the MPO activity levels in comparable bodily samples from the ~~general population or a select population of control~~ subjects.
5. (currently amended) The method of claim 1, wherein said predetermined value is a plurality of predetermined MPO activity level ranges that are based on the MPO activity levels in comparable bodily samples from the ~~general population or a select population of control~~ subjects.
6. (canceled)
7. (previously presented) The method of claim 1, wherein the levels of myeloperoxidase mass in the test subject's bodily sample is determined by an immunological technique.
8. (currently amended) The method of claim 1, wherein said predetermined values is a single normalized value or a range of normalized values and is based upon the MPO mass levels in comparable bodily samples from the ~~general population or a select population of control~~ subjects.
9. (currently amended) The method of claim 1, wherein said predetermined value is a single representative value or a range of representative values and is based upon the MPO mass levels in comparable bodily samples from the ~~general population or a select population of control~~ subjects.

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10. (previously presented) The method of claim 1, wherein said predetermined value is a plurality of predetermined MPO mass level ranges which are based on the MPO mass levels in comparable bodily samples from the ~~general population or a select population of~~ control subjects.

11-22 canceled

23. (currently amended) A method of assessing a test subject's risk of ~~developing or~~ having atherosclerotic cardiovascular disease, comprising

comparing levels of myeloperoxidase in blood, serum, plasma, blood, leukocytes selected from the group consisting of neutrophils, monocytes, sub-populations of neutrophils, sub-populations of neutrophils, and sub-populations of monocytes, or any combination thereof from the test subject with levels of myeloperoxidase in blood, serum, plasma, blood leukocytes selected from the group consisting of neutrophils, monocytes, sub-populations of neutrophils, sub-populations of neutrophils, and sub-populations of monocytes, or any combination thereof from a population of control subjects diagnosed as not having the disease;

wherein the levels of myeloperoxidase in blood, serum, plasma, ~~circulating blood~~ leukocytes, or any combination thereof from the test subject relative to the levels of myeloperoxidase in blood, serum, plasma, ~~circulating blood~~ leukocytes or any combination thereof from the population of control subjects is indicative of the extent of the test subject's risk of ~~developing or~~ having atherosclerotic cardiovascular disease.

24. canceled.

25. (previously presented ) The method of claim 1, wherein the test subject is a non-diabetic, non-hypertensive, non-smoker.

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26. (currently amended) A method of assessing a test subject's risk of developing a complication of atherosclerotic cardiovascular disease comprising:

determining levels of myeloperoxidase (MPO) activity, myeloperoxidase (MPO) mass, or both in blood, serum, plasma, blood leukocytes selected from the group consisting of neutrophils and monocytes, or any combination thereof from the test subject;

wherein elevated levels of MPO activity or MPO mass or both in blood, serum, plasma, blood leukocytes or any combination thereof of the test subject as compared to levels of MPO activity, MPO mass, or both, respectively in blood, serum, plasma, blood leukocytes or any combination thereof obtained from control subjects indicates that the test subject is at risk of developing a complication of atherosclerotic cardiovascular disease.

27. (canceled)

28. (previously presented) The method of claim 23, wherein the level of myeloperoxidase in one or more populations of leukocytes in the test subject's blood is determined by an assay which involves exposing the blood leukocytes to a peroxidase substrate and subjecting the substrate exposed blood leukocytes to flow cytometry; and

wherein the level of myeloperoxidase in the test subject's one or more populations of blood leukocytes is correlated with one or more flow cytometry parameters.

29. (previously presented) The method of claim 26, wherein the test subject's risk of developing a complication of atherosclerotic cardiovascular disease is determined by comparing levels of myeloperoxidase mass in the test subject's bodily sample to levels of myeloperoxidase mass in comparable samples obtained from a control population.

30. (canceled)

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31. (previously presented) A method for characterizing a test subject's risk of having atherosclerotic cardiovascular disease, comprising:

determining levels of myeloperoxidase (MPO) activity, myeloperoxidase (MPO) mass, or both in a bodily sample from the test subject, wherein the bodily sample is blood, serum, or plasma, and

wherein elevated levels of MPO activity or MPO mass or both in the subject's bodily sample as compared to levels of MPO activity, MPO mass or both, respectively, in comparable bodily samples obtained from a population of control subjects indicates that the test subject is at risk of having atherosclerotic cardiovascular disease.

32. (previously presented) The method of claim 23 wherein the level of myeloperoxidase in one or more populations of the test subject's circulating leukocytes is determined by an assay which employs an antibody that binds to myeloperoxidase and flow cytometry.

33. (previously presented ) A method of characterizing a test subject's risk of having atherosclerotic cardiovascular disease comprising:

determining levels of myeloperoxidase (MPO) activity, myeloperoxidase (MPO) mass, or both in a bodily sample from the test subject, said bodily sample being blood, serum, plasma, blood leukocytes or any combination thereof;

wherein a test subject whose bodily sample contains levels of MPO activity or MPO mass or both that are higher than a control value based on levels of MPO activity, MPO mass or both, respectively, in comparable bodily samples obtained from a population of control subjects is at greater risk of having cardiovascular disease than a test subject whose bodily sample contains levels of MPO activity or MPO mass or both that are equal to or less than the control value.

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34. (New) A method for characterizing a test subject's risk of developing atherosclerotic cardiovascular disease, comprising:

determining levels of myeloperoxidase (MPO) activity, myeloperoxidase (MPO) mass, or both in a bodily sample from the test subject, said bodily sample being blood, serum, plasma, blood leukocytes selected from the group consisting of neutrophils, monocytes, and a combination thereof,

wherein elevated levels of MPO activity or MPO mass or both in the bodily sample of the test subject as compared to at least one value based on levels of MPO activity, MPO mass or both, respectively, in comparable bodily samples obtained from control subjects diagnosed as not having the disease indicates that the test subject is at risk of developing atherosclerotic cardiovascular disease.

35. (new) The method of claim 34, wherein levels of myeloperoxidase activity in one or more populations of leukocytes in the test subject's blood is determined by an assay which employs a peroxidase substrate and flow cytometry.

36. (new) The method of claim 3, wherein the levels of myeloperoxidase mass in the test subject's bodily sample is determined by an immunological technique.

37. (new) A method for characterizing a test subject's risk of developing atherosclerotic cardiovascular disease, comprising:

determining levels of myeloperoxidase (MPO) activity, myeloperoxidase (MPO) mass, or both in a bodily sample from the test subject, said bodily sample being blood, serum, plasma, blood leukocytes selected from the group consisting of neutrophils, monocytes, sub-populations

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of neutrophils, sub-populations of neutrophils, and sub-populations of monocytes or any combination thereof

wherein elevated levels of MPO activity or MPO mass or both in the bodily sample of the test subject as compared to at least one value based on levels of MPO activity, MPO mass or both, respectively, in comparable bodily samples obtained from control subjects diagnosed as not having the disease indicates that the test subject is at risk of developing atherosclerotic cardiovascular disease.

38. (new) The method of claim 37, wherein levels of myeloperoxidase activity in one or more populations or sub-populations of leukocytes in the test subject's blood is determined by an assay which employs a peroxidase substrate and flow cytometry.

39. (new) The method of claim 37, wherein the levels of myeloperoxidase mass in the test subject's bodily sample is determined by an immunological technique.